DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

March 12, 2004

WARNING LETTER NO. 2004-NOL-16

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Bobby J. Guidry, President and CEO
Processors, Inc.
1093 Henderson Highway
Breaux Bridge, Louisiana 70517

Dear Mr. Guidry:

We inspected your firm, Processors, Inc., located at 1093 Henderson Highway, Breaux Bridge, Louisiana, on November 18 and 19, 2003. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products." In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, fishery products produced at your firm are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find the Act and the Seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations are as follows:

1. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor sufficiently the following areas or sanitation identified in 21 CFR 123.11(b):

   a. Your firm failed to adequately monitor the condition and cleanliness of food contact surfaces as evidenced by:

      - The presence of yellow and black filth or residue on the interiors and hand contact areas of product holding containers.

Washing and Sanitizing of

- The presence of black filth or residues on food contact surfaces of processing conveyer belts, heading equipment, and the ice auger.

- The presence of green filth or residues on food contact surfaces of IQF and grading equipment.

- The presence of filth or residues on food contact surfaces such as the fillet machine and ice shovel.

b. Your firm failed to adequately monitor the protection of food and packaging materials from contaminants as evidenced by:

- An exposed dear head stored on top of box of finished product next to plastic bags of breaded product in a freezer.

- The presence of rust on hose hand-spray nozzles and handles.

- The presence of exposed insulation and wall interiors in the ice room.

- The presence of trash stored adjacent to packing cases.

- The presence of pooled discharge on the floor near the IQF processing area and the ice room.

c. Your firm failed to adequately monitor the prevention of cross-contamination from insanitary objects to food as evidenced by:

- The presence of filth in sink water used to sanitize gloves and processing equipment, and for employee hand-washing.

- The accumulation of trash and waste throughout the processing areas.

2. You must maintain sanitation records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for the following areas of sanitation identified in 21 CFR 123.11(b) in your processing of catfish and catfish products: the proper labeling, storage, and use of toxic compounds; the exclusion of pests from the processing facility; the safety of water that comes in contact with food or is used to make ice; the maintenance of hand washing, hand sanitizing, and toilet facilities; and, the control of employee health conditions that could result in microbiological contamination of food and food contact surfaces.

We may take further action if you do not correct these violations promptly. For instance, we may seize your product(s) and/or enjoin your firm from operating.

We are aware that at the close of the inspection you made a verbal commitment to correct the deviations. Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct the deviations.

You should include in your response documentation such as copies of your revised HACCP plan(s), HACCP monitoring records, and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Current Good Manufacturing Practice regulations, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Ms. Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483